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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,016	07/25/2005	Yasuhide Nakayama	SHI-027	5028
32628 7590 11/17/2009 KANESAKA BERNER AND PARTNERS LLP 1700 DIAGONAL RD SUITE 310 ALEXANDRIA, VA 22314-2848				
EXAMINER STROUD, JONATHAN R				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
11/17/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/525,016

**Applicant(s)**

NAKAYAMA ET AL.

**Examiner**

JONATHAN STROUD

**Art Unit**

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-31 and 79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-31 and 79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)  
Paper No(s)/Mail Date 06/05/2009, 07/02/2009
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed 06/16/2009, with respect to the rejection(s) of claim(s) 25-31 in view of Takehisa JP 11-299901, have been considered, but are moot in light of the new grounds of rejection.

Takehisa JP 11-299,901 teaches the formation of a polymer formed with pores via a mandrel pulling-up process, then applied to a stent, as applicant discloses in remarks.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-31 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takehisa JP 11-299,901, via translated abstract provided by applicant, via applicant's admissions in remarks filed 06/16/2009, and via machine translation provided by the Japanese Patent Office, further in view of Edwin 6,245,099.

1. Re claims 25, 26, and 79, Takehisa discloses a method for preparing a stent matrix such as the one discussed in the abstract, comprising preparing a tubular stent matrix, 10, forming flexible solid polymer layers on the stent matrix, 19, and perforating a plurality of fine through pores at portions only where the stent matrix does not exist,

fig. 2; wherein forming the layers comprises a step of forming a polymer film by impregnating a mandrel into a liquid resin material, para. [0016], for forming the polymer film and pulling up on the mandrel, and equalizing the thickness of the polymer film by pulling up on the mandrel in a vertical direction, para. [0033].

Takehisa does not disclose first forming a perforated polymer layer on a mandrel, adding a stent element to that composition on the mandrel, then forming a second layer on top of that element.

Edwin discloses forming a first polymer layer on a mandrel, adding a stent element to that mandrel, then forming a second layer on top of that element, for the purpose of forming bonded layers of polymeric material with an internal structural member present, to enhance cellular penetration for rapid healing.

Re claim 27 and 29, polyurethane is disclosed as the preferable first material, para. [0016].

Re claim 28, another polymer layer can be added to be impregnated with drugs, para. [0009].

Re claim 30 and 31, laser machining can form fine through pores in the surface, abstract.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Takehisa in view of Edwin, in order to first form the perforated element of Takehisa via controlling the pulling-up speed, then applying an expandable stent element over that element, then forming a second layer outside of the first, for the purpose of creating a polymer-material stent to enhance cellular penetration for rapid

healing but maintain the strength of a metallic or solid member, and to prevent foreign body response on the internal lumen of the member. Furthermore, it has been held that a duplication of parts is obvious to one of ordinary skill in the art, and is obvious without any added reason or motivation. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). See MPEP 2144.04 VI (B).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on 8-4, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner, Art Unit 3774

/Jonathan R Stroud/  
Examiner, Art Unit 3774